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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,872

Applicant(s)

MILNE EDWARDS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-12,24,25,28,29 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 1,9-12,24,25,28,29,42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-41,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1, 9-12, 24, 25, 28, 29 and 37-45 are pending.

Applicants' amendment filed on January 23, 2003 (Paper No. 15) is acknowledged.

Claims 38-43 have been amended, and new claims 44-45 have been added. Claims 1, 9-12, 24, 25, 28, 29, 42 and 43 are non-elected inventions, thus, are withdrawn from consideration.

Therefore, claims 37-41, 44 and 45 are examined.

2. Formal drawings (Paper No. 16) have been submitted, however, two drawings are objected by Draftsman (see attached Form 948).

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 38-40 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in Paper No. 15.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 37-41, 44 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claims are directed to a purified polypeptide comprising an amino acid sequence of a mature or full-length polypeptide of SEQ ID NO:253 (claims 37-40 and 44) and a purified polypeptide

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comprising a full-length or mature amino acid sequence encoded by a human cDNA of Clone 105-095-2-0-G11-CS in ATCC accession number PTA-1218 (claims 41 and 45). The polypeptide of SEQ ID NO:253 along with SEQ ID NO:243 are disclosed as members of glycerophosphodiester phosphodiesterase (GP-PDE) protein family, interact with RGS 16 (Regulator of G protein Signaling) protein, and as such, play important roles in both lipid metabolism and in G protein signaling (page 347, lines 1-3). The specification (page 346), discloses that the 331-amino-acid protein of SEQ ID NO:243 is highly homologous to the putative GP-PDE MIR-16 (membrane Interacting protein of RGS16) protein (GenBank accession no. AAF65234), and the protein is likely a variant of the MIR16 protein, and a BLAST search with the amino acid sequence of SEQ ID NO:243 further indicates the protein is homologous to GP-PDEs of *E. coli* and *Haemophilus influenzae* (page 346, line 3-12). The specification also indicates MIR 16 protein, which is homologous to the protein SEQ ID NO:243 was identified in a yeast two hybrid screen of pituitary cell cDNA library using the RGS 16 protein as a bait (Zheng et al., Proc. Natl. Acad. Sci. 97, 3999-4004 (2000); page 346, lines 20-23), and from sequence alignments of MIR16 with other GP-PDEs (Fig. 2 in Zheng et al. (2000)), the N-terminal region of MIR16 (amino acids 70-150), immediately after the putative signal peptide, is highly conserved (40-61% similarity), suggesting that it may contain residues critical for catalytic activity, i.e., the catalytic site. The putative enzymatic activity of MIR16 and its interaction with RGS16 suggest that it may play important roles in lipid metabolism and G protein signaling (Page 346, lines 27-33). However, the sequence alignments of SEQ ID NO:253 (108 amino acids) with MIR16 (331 amino acids) and SEQ ID NO:243 (331 amino acids) indicate that SEQ ID NO:253 has 79.3% sequence identity with MIR16 or SEQ ID

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NO:243 (see attached sequence comparison), and the amino acids 1-87 of SEQ ID NO:253 are matched with MIR16 or SEQ ID NO:243 except for positions 75 (residue 44) and 76 (residue 45), but, the amino acids 88-108 of SEQ ID NO:253 (LRMEQQAWSWTLSLLLTGFLS) are not matched with those of MIR16 or SEQ ID NO:243 (AAKNGATGVELDIEFTSDGIP). From the sequence comparison of SEQ ID NO:253 to MIR16, it appears SEQ ID NO:253 only contains a portion (residues 70-87) of the putative catalytic site (residues 70-150), thus it is not known whether SEQ ID NO:253 is a functional protein without indicating its GP-PDE activity.

Furthermore, the binding region of MIR16 to RGS 16 protein has not been identified, thus it is not clear whether SEQ ID NO:253 contains the binding region to RGS 16 protein. Since SEQ ID NO:253 as being a functional GP-PDE and the binding of SEQ ID NO:253 to RGS 16 protein have not been demonstrated in the specification, thus, its functional role is not established. For these reasons, the instant invention does not possess a specific or a well-established utility, although there is a general utility that is applicable to the broad class of GP-PDE. The utility is not a substantial utility because it requires further research to identify or reasonably confirm a "real world" context of use. Basic research to characterize the claimed invention, use in an assay to identify modulators of the instant invention, or production of antibodies to identify other related proteins do not constitute substantial utilities.

In response, applicants indicate SEQ ID NO:253 is a novel splice variant of MIR16 as indicated in the specification (page 346, paragraph 2) and the attached alignment, the 87 N-terminal amino acids of SEQ ID NO:253 are identical to the 87 N-terminal amino acids of MIR16, but SEQ ID NO:253 is not a novel member of GP-PDE family to which MIR16 belongs (page 4 of the response). Applicants further assert that splice variants are rarely involved in

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different biological pathway, e.g., splice variants rarely interact with unrelated binding partners, and it is established MIR16 interacts with RGS protein (Zheng et al., Proc. Nat. Acad. Sci. 97, 3999-4004 (2000)), accordingly, because SEQ ID NO:253 is a splice variant of a protein interacting with RGSs, one skilled in the art would reasonably conclude SEQ ID NO:253 interacts with RGS, thus SEQ ID NO:253 can be used to detect RGSs such as RGS 16 in various assays (pages 4 –5 of the response). Applicants also indicate because the 87 N-terminal amino acids of SEQ ID NO:253 are identical to the 87 N-terminal amino acids of MIR16, thus, the antibodies prepared against SEQ ID NO:253 would be expected to bind not only SEQ ID NO:253, but such antibodies would also bind related polypeptides such as MIR16. Accordingly, one skilled in the art would recognize that antibodies raised against SEQ ID NO:253 would have utility in the detection or isolation of GP-PDEs such as MIR16. Therefore, SEQ ID NO:253 and the polypeptides of claims 37-41 have a specific, credible and substantial utility (page 5 of the response). Applicants' response has been fully considered, however, the argument is not found persuasive because the specification has not demonstrated the binding of SEQ ID NO:253 to RGS protein, nor has established the function of SEQ ID NO:253. The prior art and the sequence alignment of SEQ ID NO:253, SEQ ID NO:243 and MIR16 clearly indicate that SEQ ID NO:253 does not contain the total residues (residues of 70-150) of the GP-PDE catalytic site, thus, it is not clear whether SEQ ID NO:253 is a functional protein. Furthermore, the binding region of MIR16 to RGS protein has not been identified, and SEQ ID NO: 253 (108 amino acids) only contains one third of the full length of MIR16 (331 amino acids), thus, it is not clear whether SEQ ID NO:253 would bind RGS protein without testing. Therefore, it is necessary to carry further experimentation to assess the binding ability of SEQ ID NO:253 to RGS protein

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and the function of SEQ ID NO:253. Although the antibodies raised against SEQ ID NO:253 can be used for the detection of SEQ ID NO:253 or related peptides as indicated in the specification (pages 70-75) and the response (page 5), since SEQ ID NO:253 only contains a portion of MIR16, it is not clear whether the antibodies prepared against SEQ ID NO:253 would detect a functional GP-PDEs without further experimentation. Since the functional role of SEQ ID NO:253 is not established, the instant invention does not possess a specific or a well-established utility as indicated in the section above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 37-41, 44 and 45 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. The Office notes that a deposit of 105-095-2-0-G11-CS clone has been deposited with the American Type Culture Collection (ATCC), Rockville, MD, has been given the accession number PTA-1218, and deposited under the Budapest Treaty. Therefore, no 35 U.S.C. 112 paragraph 1 rejection has been entered even though it is apparent that the claimed deposit material is essential to the claimed invention and the deposit is necessary for an adequate written description and enablement for the claimed invention. Applicant should provide a photocopy of the receipt of the certificate of deposit.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 contains the trademark/trade name ATCC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe "American Type Culture Collection" and, accordingly, the identification/description is indefinite.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 26, 2003

Christopher S. F. Low
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